DETAILED ACTION

This Official Action is in response to the responses filed 12/16/09 and 3/22/10 and the interview of 3/18/10. In the interview it was discussed amendments to the claims that may make the instant application allowable. The response filed 3/22/10 accurately summarizes the substance of the interview. However claims 15-17 are rejected below.

Claims 1, 2,5-9, 11-13, 15-20 are pending and under examination.

Claims 1, 2, 5-9, 11-13, 19, and 20 are allowed.

Any rejection or objection made in the previous official Action and not repeated herein is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the

time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claimed invention is drawn to the inhibition of HCV mediated translation in a person via the administration of any compound that may bind ribosomal protein S5 and inhibits binding to HCV IRES.

The specification discloses SEQ ID NO: 1, 4, and 5 which correspond to synthetic IRES sequences. A Method utilizing these sequences meet the written description provisions of 35 USC 112, first paragraph. However, the claims are directed to encompass sequences that are mutated, allelic variants, as well as any compound that may bind an S5 protein and provide the required effect of the claimed invention. None of these sequences or compounds meet the written description provision of 35 USC 112, first paragraph as used in the instant methods. The specification provides insufficient written description to support the genus encompassed by the claim. The instant specification provides guidance and a description of specific RNA sequences that have a specific biological activity. The specification has not shown any other compounds that provide for the effect required by the instant claims. The disclosure of 3 sequences, which are closely related, does not provide sufficient description of the numerous other compounds embraced for use in the instant methods. One in the art would no immediately envision the structure of the compounds embraced for use in the instant method based on the disclosure of the three species above. One in the

art is left to find these sequences without knowledge of there expected structures where the expected structure would provide an expected function as required by the instant claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 1, 4, and 5, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, or small molecules or any other compound embraced by the claims regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

One in the art is left to find a vast number of compounds embraced by the claims where only 3 closely related compounds have been described.

Therefore, only methods utilizing SEQ ID NO: 1, 4, or 5 but not the full breadth of the claim meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory

action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on (571) 272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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